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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,695	02/19/2004	Maria A. Glucksmann	MPI04-002OMNIM	4730

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,695	GLUCKSMANN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Currently, claims 1-18 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 7, drawn to a nucleic acid, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 435, subclass 69.1.

II. Claims 4 and 6, drawn to a polypeptide, and a fusion protein thereof, classified in class 530, subclass 350.

III. Claim 5, drawn to an antibody, classified in class 530, subclass 387.9.

IV. Claims 8 and 9 in part, drawn to a method for detecting the presence of a nucleic acid, and a kit for the detection, classified in class 435, subclass 6.

V. Claims 8 and 9 in part, drawn to a method for detecting the presence of a polypeptide, and a kit for a binding compound for the detection, classification depending upon the chemical entity of the binding compound.

VI. Claim 10, drawn to a method for identifying a compound binding to or modulating the activity of the polypeptide, classified in class 435, subclass 7.1.

VII. Claim 11, drawn to a method for modulating the activity of the polypeptide, classification depending upon the chemical entity of the binding compound.

VIII. Claim 12 in part, drawn to a method for identifying a compound for treatment, wherein the compound is capable of modulating the nucleic acid expression, classification depending upon the method steps.

IX. Claim 12 in part, drawn to a method for identifying a compound for treatment, wherein the compound is capable of modulating the polypeptide activity, classification depending upon the method steps.

X. Claims 13 and 15, drawn to a method of identifying a nucleic acid molecule or a subject associated with a disorder, classified in class 435, subclass 6.

XI. Claim 14, drawn to a method of identifying a polypeptide associated with a disorder, classified in class 436, subclass 501.

XII. Claims 16-18 all in part, drawn to a method of treatment with a modulator or the nucleic acid or the polypeptide, wherein the modulator is a small molecule, classification depending upon the chemical entity of the small molecule.

XIII. Claims 16-18 all in part, drawn to a method of treatment with a modulator or the nucleic acid or the polypeptide, wherein the modulator is a peptide, classified in class 514, subclass 2.

XIV. Claims 16-18 all in part, drawn to a method of treatment with a modulator or the nucleic acid or the polypeptide, wherein the modulator is an antibody, classified in class 424, subclass 139.1.

XV. Claims 16-18 all in part, drawn to a method of treatment with a modulator or the nucleic acid or the polypeptide, wherein the modulator is an antisense nucleic acid, classified in class 514/536, subclass 44/24.5.

XVI. Claims 16-18 all in part, drawn to a method of treatment with a modulator or the nucleic acid or the polypeptide, wherein the modulator is a ribozyme, classified in class 536, subclass 24.5.

XVII. Claims 16-18 all in part, drawn to a method of treatment with a modulator or the nucleic acid or the polypeptide, wherein the modulator is a nucleic acid or a gene therapy vector, classified in class 514, subclass 44.

The inventions are distinct, each from the other because:

The nucleic acid of Invention I is related to the polypeptide of Invention II by virtue of encoding same. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecules and proteins are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The nucleic acid of Invention I is distinct from and unrelated to the antibody of Invention III because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct from and unrelated to the antibody of Invention III because the antibody may be neither made by nor used in the method.

The nucleic acid of Invention I can be related to Inventions IV, X and XVII as product and process of use if the nucleic acid is used in the method of detection. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid as claimed may be used for the production of the polypeptide of Invention II.

Invention I is distinct from and unrelated to Inventions V-IX and XI-XVI, wherein the products of Invention I are neither made by nor used in the methods of Inventions V-IX and XI-XVI, and wherein each does not require the other.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

The polypeptide of Invention II is related to Inventions VI, VII and XI as product and process of use if the nucleic acid is used in the method of detection. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide as claimed may be used for generating the antibody of Invention III.

Invention II is distinct from and unrelated to Inventions IV, V, VIII-X and XII-XVII, wherein the products of Invention I are neither made by nor used in the methods of Inventions IV, V, VIII-X and XII-XVII, and wherein each does not require the other.

The antibody of Invention III is related to Inventions V and XIV as product and process of use if the nucleic acid is used in the method of detection. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody as claimed may be used for the purification of the polypeptide of Invention II.

Invention III is distinct from and unrelated to Inventions IV, VI-XIII and XV-XVII, wherein the products of Invention I are neither made by nor used in the methods of Inventions IV, VI-XIII and XV-XVII, and wherein each does not require the other.

Inventions IV-XVII are drawn to independent methods, wherein each of the methods has different process steps, different active agents, different starting and ending points, and is for a different purpose, such that they require separate searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, regardless of which Invention applicants elect above, further **restriction** is required under 35 U.S.C. 121:

A. One specific nucleic acid sequence with SEQ ID NO from the following: SEQ ID NO:1, 4, 6, 13, 15, 16, 18, 32, 34, 35, 37, 47 or 49.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-XVII, and an election of the invention from Group A or B, to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention. Applicant is advised that neither I-XVII nor A is species election requirement; rather, each of I-XVII and A is a restriction requirement.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
AU1646
5/14/06